JUL 1 1 2013

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Date Summary Prepared:	February 1, 2013
Trade Name:	EXTENSION Clinical Alert Notification solution
Common Name:	Network and communications middleware
Device Class:	Class II
Product Code:	MSX
Classification Name:	System, Network and Communications, Physiologic Monitors
Substantially Equivalent Devices:	Ascom Cardiomax, K103634

Description of Clinical Alert Notification

The EXTENSION Clinical Alert Notification solution is a closed loop communications system that interfaces with health care information systems and medical devices to provide a secondary means of annunciating and displaying patient alarm text and other information to mobile health care workers. The EXTENSION Clinical Alert Notification solution alerts and informs the clinician about patient alarms. The EXTENSION Inc. device is not intended to replace any part of the patient monitoring system or patient monitoring procedures already existing for the medical devices interfaced with the EXTENSION Clinical Alert Notification solution.

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Intended Use/Indications for Use

The EXTENSION Clinical Alert Notification solution is a closed loop communications system that interfaces with health care information systems and medical devices to provide a secondary means of annunciating and displaying patient alarm text and other information to mobile health care workers that is important to patient care, nursing vigilance and overall hospital operations. The EXTENSION Clinical Alert Notification solution alerts and informs the clinician about critical patient alarms by drawing an identified individual's attention to a defined patient condition in a timely manner without requiring them to be at or near the bedside medical devices or central station displays. The EXTENSION Clinical Alert Notification solution is not intended to replace any part of the patient monitoring system or procedures already existing for the medical devices interfaced with the EXTENSION Clinical Alert Notification solution.

The EXTENSION Clinical Alert Notification solution is limited to use by qualified medical professionals who have been trained on the use of the device. It is intended for use in hospital and hospital type acute care environments and is not for home use.

Technology

The EXTENSION Clinical Alert Notification solution is made up of standard telecommunications and information technology. EXTENSION develops the application software that runs on a virtual machine and is accessed by client devices (PC computers running web browsers, wireless voice over IP phone handsets).

The EXTENSION Clinical Alert Notification solution functions and transmits data similarly to the predicate devices. The EXTENSION Clinical Alert Notification solution and predicate devices use similar data transmission and communications technologies.

Types of medical devices supported	Patient monitors, infusion pumps, ventilators, and similar devices	Designed for a variety of therapeutic, diagnostic and monitoring medical devices. Initial interface for patient monitors.
Remote access to medical device data via internet	Yes	Yes
Hardware wired connection	1. Medical device connects to radio. 2. Router switch connects to access point 3. Router switch connects to mobile device switch (phone or other endpoint system) 4. Router switch connects to server 5. Router switch connects to client devices (PCs and displays)	Same
Hardware wireless connection	1. Radio connects to access point 2. Phone or other endpoint device transmitters connect to mobile devices	Same

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Wireless transmission technology	1. IEEE 802.11a/b/g/n 2. DECT/IEEE 802.11a/b/g/n for handsets or PDAs	Same
Hardware components	Standard telecommunications and IT components: 1. Wireless VoIP handset or other endpoint device 2. Access point 3. Switch/router 4. Server 5. Phone switch using access point(s) 6. Pagers and/or handsets, PDAs	Same

Test Summary

The EXTENSION Clinical Alert Notification solution complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the EXTENSION Clinical Alert Notification solution:

- Risk analysis
- Design reviews
- Component level testing
- System level testing
- Performance testing
- Safety testing
- Usability and validation testing

Conclusions

The information in this 510(k) submission demonstrates that the EXTENSION Clinical Alert Notification solution is substantially equivalent to the predicate devices as a supplementary alarm system, with respect to safety, effectiveness, and performance.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 11, 2013

Extension , Inc
c/o Mr. Tim Gee
7250 SW 154th Terrace
Beaverton, OR 97007

Re: K130339
Trade/Device Name: Clinical Alert Notification System
Regulation Number: 21 CFR 870.2300
Regulation Name: System, Network and Communication, Physiological Monitors
Regulatory Class: Class II
Product Code: MSX
Dated: June 12, 2013
Received: June 13, 2013

Dear Mr. Tim Gee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Section 4. Indications for Use Statement

K130339

510(k) Number (if known): Page 1 of 1

Device Name: EXTENSION Clinical Alert Notification

Indications for use:

The EXTENSION Clinical Alert Notification solution is a closed loop communications system that interfaces with health care information systems and medical devices to provide a secondary means of annunciating and displaying patient alarm text and other information to mobile health care workers that is important to patient care, nursing vigilance and overall hospital operations. The EXTENSION Clinical Alert Notification solution alerts and informs the clinician about critical patient alarms by drawing an identified individual's attention to a defined patient condition in a timely manner without requiring them to be at or near the bedside medical devices or central station displays. The EXTENSION Clinical Alert Notification solution is not intended to replace any part of the patient monitoring system or procedures already existing for the medical devices interfaced with the EXTENSION Clinical Alert Notification solution.

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Prescription Use ____X____ **And/Or** **Over-the-Counter-Use:** _

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.07.11 14:25:09 -04'00'

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